

Applicant: Ralph Leonard

Originally submitted 1-17-02, Today's date: 4-11-02.

Invention submitted for application: Selection Of Optimal Medication Methodology (SOOMM)

CLAIM or CLAIMS

- I We claim as our invention the systematic process of assigning a quantitative score to each combination of medical conditions the risks and benefits (indications and contraindications, respectively) of all relevant pharmaceutical and non-pharmaceutical classes of therapies for a given disease process described above as Selection Of Optimal Medication Methodology.
 - A. Sub-claim: the SOOMM system as described in Claim I may use from four to an infinite number of cells within a matrix to determine various nuances of indications and contraindications, but the suggested system is for 4x4 with a 3x3 inner space of 9 active cell scores.
 - B Sub-claim: the SOOMM system as described in Claim I uses the term class to refer to a group of members within a therapeutic category which are considered homogenous enough to share the same indication and contraindication scores, and may be categorized based on existing classifications (e.g., as proposed by the FDA) but also based on de novo schemes created by those who implement it with specific details.
 - C. Sub-claim: the SOOMM system as described in Claim I uses the term "medical condition" to refer to any diagnosed disease or highly probably disease as based on objective data extracted from laboratory or other sources.
- II. We claim as our inventions that the SOOMM system may be further augmented by additional external rules embodied in authoritative guidelines that ranks classes for their role in a given disease, all other things being equal.
- III. We claim as our invention that the SOOMM process of choosing the best therapeutic class may be applied to therapies within a class where specific distinguishing indications and contraindications exist. The lowest acceptable limit of risks and benefits may be determined by the end-user, but in the 9-cell model illustrated here we recommend values of 5 or lower be cause for giving no recommendation and allowing the clinician to chose a therapy.
- IV. We claim that the SOOMM system only requires the patient's medical conditions be entered in such a way that the system may be applied (e.g., populate specific data fields or other).
- V. We claim as our invention that the subsequent choices between products within a given class chosen by the SOOMM system (i.e., those in a class are considered equal), may be further ranked according to other factors such as a third-party payer's preferences, cost of the

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medication and the user's prior picks. Such subsequent ranking may be done after a class is selected by further input by the user (who selects how things are sorted).

- VI. We claim as our invention that the SOOMM system may be implemented in a variety of computational devices, as either software or hardware. This implementation can be executed on mainframe, personal (desktop or laptop) computers, mobile computing devices (such as Personal Digital Assistants or mobile phones), delivered via wired or wireless network technology using servers or their equivalents via an intranet or internet.
- VII. We claim as our invention that the actual user interface could be graphical or non-graphical, that multiple pointing (mouse, stylus, light-pen etc.) and data entry modalities (keyboard, speech to text conversion, electronic importing, etc.) can also be supported.
- VIII. We claim as our invention that the SOOMM system could be written within a broader program such as an electronic medical record designed by another group.
- IX. We claim as our invention that the SOOMM system could be written as a stand-alone program that could ask the user or others with information and who are permitted to enter it and that other relevant data may be imported electronically, scanned or via other means such that a complete list of the patient's medical conditions and problems is maintained.
- X. We claim as our invention that the SOOMM system can be applied to patients with multiple medical conditions, diagnoses and concomitant medications.
- XI. We claim as our invention that the SOOMM system can use, for medical conditions, laboratory or other objective data that defines a medical condition rather than having that stated only in a problem list.
- XII. We claim as our invention that the SOOMM system is fundamentally different than an inference engine, neural network or those less rigorous and predictable such as "fuzzy logic" that employ random or statistical probabilities rather than rigorous protocols.
- XIII. We claim as our invention that the SOOMM system can be written in any computer programming language, either existing or future developed, that can express the concepts described.
- XIV. We claim as our invention that the SOOMM system could run on any operating system that can in turn support a computer programming language.
- XV. We claim as our intervention that the SOOMM system may be updated such that the rules may reflect the accepted knowledge of the day and would not be influenced by the prior

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choices of the user. However, where there is more than one popular recommendation (as in the case when multiple guidelines exist but are contradictory), the user may be given the option of selecting which guidelines s/he wishes to have used in the SOOMM.

- XVI. We claim as our invention that the specific recommendations given by SOOMM may only be as accurate as the data on which they are based. Thus, if the accuracy of published research is poor and has been wrongly adopted into recommendations, FDA statements and other data, this will be reflected in the SOOMM recommendations. However, such a limitation is inherent in any medical field and would not be accentuated by SOOMM.
- XVII. We claim as our invention that the SOOMM system could be applied to classes of pharmaceutical and non-pharmaceutical treatments that exist or are not discovered, invented or patented once indication and contraindication ratings have been assigned.
- XVIII. We claim as our invention that the SOOMM system could be applied to any disease and medical conditions that exist or may be discovered in the future.
- XIX. We claim as our invention that the dose of a therapy/medication within a class selected by the SOOMM system may be further modified or suggested based on other parameters provided by manufacturers.
- XX. We claim as our invention that the SOOMM system may have additional rules placed upon the selection of therapies from the first ranking of therapies such that additional therapies may be added (e.g., would take the highest score therapy if there were no therapies of any class for given problem; would take the second highest score if a patient were already on the best therapy at a maximal or adequate dose and target control is still not being reached) or lesser ranking ones identified and suggested to be deleted.